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Version 12

Division of Tuberculosis Elimination Outbreak Response Plan *Working Draft*

**National Center for HIV, STD, and TB Prevention
Centers for Disease Control and Prevention**

2002 Writing Committee:

**Gabrielle Benenson
Kashef Ijaz
John Jereb
Olga Joglar
Peter McElroy
Joseph Scavotto**

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Defining a Tuberculosis Outbreak: Introduction

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A “tuberculosis outbreak” usually is defined from a short-term perspective, for example, as observed for a period of several months to several years. Viewed from the long-term perspective, over a period of decades, all tuberculosis cases are part of an extended outbreak, because they are the result of human-to-human transmission. Defining an outbreak depends on epidemiological and social context, and discovering one depends on a series of public health events and outcomes.

In populations where tuberculosis is very common, recent transmission constantly causes clusters of two or more individuals who have tuberculosis and who generally are linked by household association. These focal clusters blend into the generally high background rate of tuberculosis, however, and public health resources rarely are diverted to these clusters away from finding cases among self-referring symptomatic patients. In contrast, when the incidence rate is less (e.g., $< 50/100,000$ population/year), the sensibility shifts. With low morbidity, the local epidemiological context demarcates certain clusters of cases as “outbreaks.” In this context, especially when cases are rare, each new case is noteworthy, and case clusters are especially distinctive.

In the United States, the convergence of several interrelated problems is making tuberculosis outbreaks more prominent and troublesome. Now that tuberculosis transmission is relatively rare in most regions, the majority of the population has not been infected – a burst of

transmission causes a disturbance prominent from the minimal baseline rate. In an ironic coincidence, the public-health systems for finding and curing tuberculosis and for investigating contacts are being reduced to a minimum in regions where the average incidence rate is low. Tuberculosis is unfamiliar now to most general health-care providers, who have difficulty in diagnosing it and in remaining aware of the current treatments and the public-health issues. Thus, delays in diagnosis and notification are more likely. With the combination of (1) delayed case detection and notification, (2) extended transmission, and (3) insufficient capacity to respond comprehensively, the ensuing case-cluster is defined here as a “tuberculosis outbreak.” The problems leading to an outbreak emerge approximately in this sequence: The likelihood is enhanced for a contagious tuberculosis patient to spend extended time with susceptible contacts; the problem is discovered after the process is well advanced; the ensuing case-cluster makes up a large fraction of the local tuberculosis incidence; and the routine capacity for a comprehensive public-health response is overwhelmed by the scope of the outbreak.

Each outbreak is a setback for tuberculosis elimination, a national objective which was adopted in 1989. In 1986, at the same time that the newly-formed Advisory Committee (now Council) for the Elimination of Tuberculosis was drafting a national plan for tuberculosis elimination, a resurgence of tuberculosis was raising alarm, and this eventually culminated in augmentation of the national tuberculosis program. An obvious feature of the resurgence and the national response to it was a series of large outbreaks of multidrug-resistant tuberculosis. The Division of Tuberculosis Elimination (DTBE) and other components of the Centers for Disease Control and

Prevention (CDC) contributed teams of investigators who assisted state and local health departments in investigating the outbreaks and formulating the interventions. Further, DTBE joined with other federal agencies in funding and planning for strengthening all tuberculosis control programs in the United States.

By 1993 the national response reversed the resurgence. Case counts have been declining since then. However, outbreaks are still occurring sporadically, and they are having a greater impact on the low-incidence jurisdictions that have small tuberculosis control programs. DTBE is committed to using the knowledge gained during the resurgence of the 1980s to join with these jurisdictions in investigating and containing tuberculosis outbreaks, enhancing and refining state and local tuberculosis control programs, and staying on course for national tuberculosis elimination. Looking to the future, DTBE is vigilant for unusual outbreaks and seeks to expand the science of tuberculosis epidemiology by studying novel or particularly troublesome outbreaks, with the goal of gaining new insights and sharing the discoveries with all tuberculosis controllers.

Guiding Philosophy

DTBE —

- acts in accordance with CDC values (accountability, respect, and integrity)
- is a national resource for health agencies and strives to serve their needs in tuberculosis control, prevention, and elimination

- fosters collaborations within CDC and with entities outside CDC
- provides the best scientific bases to guide program policies and activities
- cultivates, strengthens, and coordinates tuberculosis control activities in other health agencies

Goals of the Outbreak Response Plan

Primary

- To assist health agencies to discover, interrupt, and prevent tuberculosis transmission

Secondary

- To build expertise in tuberculosis epidemiology, diagnosis, and treatment at all health agencies, including DTBE
- To assess the impact of investigations and interventions carried out under this Outbreak Response Plan
- To participate in the evaluation of tuberculosis program functions, costs, and effectiveness
- To establish an accountable system of DTBE communication, evaluation, response, and tracking of tuberculosis transmission situations
- To help partner agencies in obtaining resources for implementing interventions, including training to build skills, and strategic programmatic changes
- To determine medium and long-term intervention needs for the interruption of tuberculosis transmission

- To contribute to the training of Epidemic Intelligence Service Officers
- To contribute to the understanding of tuberculosis transmission dynamics, diagnostic tools, therapeutics, *M. tuberculosis* virulence and human tuberculosis immunity

Procedures

I. Receiving Notifications: Report of Tuberculosis Transmission

DTBE may be informed of instances of tuberculosis transmission in any number of ways. Field Services and Evaluation Branch (FSEB) personnel may be consulted, or they may learn of the situation as part of routine communications with their constituency in state and local health departments. Personnel in the Surveillance, Epidemiology, and Outbreak Investigations Branch (SEOIB) also may be consulted concerning an epidemiologic or surveillance question, and project officers and duty officers in any branch may learn of such instances as part of their activities. All DTBE personnel are responsible for ensuring that complete and accurate communication concerning such instances is achieved according to the procedures outlined herein. Sources for initial notifications include state or local health department personnel, private health care providers, personnel from local, state, or federal agencies, media reports, and lay citizens. DTBE staff may learn of tuberculosis case clusters (potentially indicating outbreaks) from analyses of tuberculosis case surveillance, genotype project databases, or other study activities. Instances in which tuberculosis transmission is suspected are to be documented and retained in DTBE tracking records regardless of the source of the information or the local or state plans for an intervention.

Listed here are some circumstances of particular concern –

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1. Infectious source patient with high-risk exposures. In this instance, a patient with infectious tuberculosis is found. In addition, there is at least one of the following circumstances:

- a. The source patient is suspected or known to have *M. tuberculosis* resistant at least to rifampin.
- b. The exposure involves contacts with HIV infection or other intrinsic (i.e., medical/immunological) risk factors for TB.
- c. The exposure involves contacts in high-risk settings (Table 1).

2. A child five years of age or less with confirmed tuberculosis for whom a source of infection is not discovered after source investigation.

3. A cluster of cases in place and time. In one or more counties in a state over a period of approximately 6 months, compared to the previous equal time span, any increase in the number of cases which is considered significant by a correspondent or by DTBE personnel.

4. A genotype cluster possibly indicating ongoing transmission.

5. Situations for which extensive tuberculosis transmission is confirmed or suspected.

These situations may involve workplaces, schools, unconventional social networks, or other circumstances in which screening for tuberculosis disease and infection involves large numbers of people or in which multiple cases are suspected.

6. Instances in which transmission is suspected or confirmed among patients in multiple states. For example, an infectious source patient has exposed persons in multiple states, or transmission has been discovered among specific members of a group that resides or travels to multiple states, such as homeless persons who visit shelters in multiple states.

7. Instances in which false-positive AFB smears or cultures are suspected. False-positive AFB smears or cultures may be responsible for mis-diagnosis of tuberculosis, and unnecessary tests, treatment, and toxicities for patients. Most false-positive AFB smears or cultures are based on laboratory cross-contamination (Table 2), but may also be due to clerical errors and mislabeling.

8. Tuberculosis problems (e.g., see above #1-7) affecting the service clientele or employees of other federal agencies, such as the Veterans Administration, the Department of Defense, and the Indian Health Service.

In each instance that such notification is received, a Report of Tuberculosis Transmission (RTT) form is to be completed (Attachment 1). The FSEB consultant responsible for the jurisdiction

concerned is responsible for completing the RTT form. Persons receiving the initial notification, for example, duty officers, should refer the correspondence to the responsible FSEB consultant (or FSEB Team Leader, if the consultant is unavailable to pursue the report), who starts the collection of the information for the RTT form. After the consultant assures the RTT form is completed with data that are readily available from state or local health authorities or are feasible to obtain within 3 business days, the form is shared with the respective FSEB Team Leader, who provides consultation and discusses obtaining additional information for the RTT. Discussions with medical officers and epidemiologists in FSEB or SEOIB at this point may be requested, at the discretion of the FSEB Team Leader. Preliminary consultation to state or local health authorities can be provided in response to immediate concerns. A more specific, comprehensive response is deferred to the Outbreak Evaluation Unit, which makes its recommendations to DTBE Office and the Director and Branch Chiefs. At preliminary stages, before the Outbreak Evaluation Unit has made recommendations and DTBE has discussed its response options, only general classes of responses should be presented to officials at the corresponding agency.

II. Outbreak Evaluation Unit

The purpose of the Outbreak Evaluation Unit (OEU) is (1) to review, on a weekly basis or more often if the load or urgent issues so warrant, all new outbreak assessments and reports compiled by FSEB and documented on the RTT form, (2) to recommend the DTBE responses or actions, (3) to review the status of ongoing assessments and reports of investigations, (4) to prepare quarterly summary reports about its activities for the Office of the Director in DTBE, and to

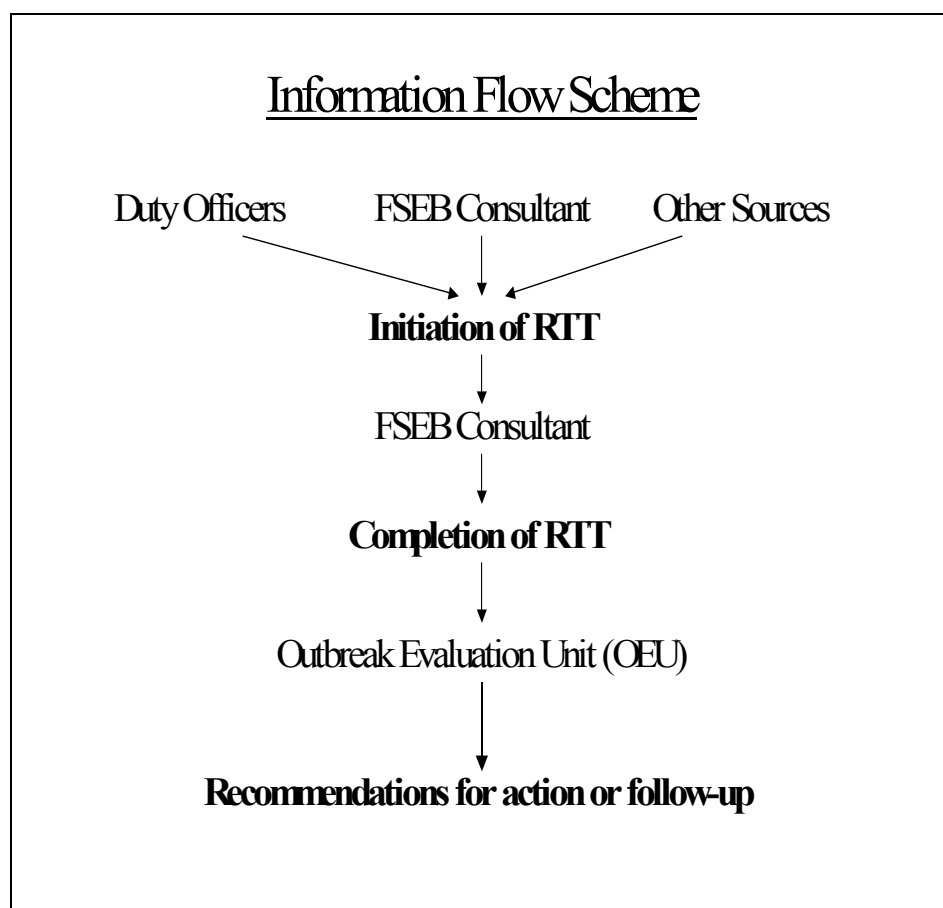
monitor its own process for quality assurance.

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Routine participants in OEU include the SEOIB Deputy Branch Chief and the Outbreak Investigation Team Leader or their delegates, the FSEB Branch Chief and both FSEB Team Leaders or their delegates, a health-education specialist from the Communications, Education, and Behavioral Studies Branch (CEBSB), and a representative from the Office of the Director, DTBE. These members comprise the core decision makers for the unit. They should invite expert consultants, such as a representative from the Division of AIDS, STD, and Tuberculosis Laboratory Research, as needed. A record keeper provides logistical support and coordinates the flow of information. The meeting is open to other participants from DTBE, and persons who are in training, such as Epidemic Intelligence Service (EIS) Officers, are encouraged to attend as observers. Usually, non-CDC personnel should not be invited, unless approved by Office of the Director and Branch Chiefs of FSEB and SEOIB, because state and local health officials ask that data from their jurisdictions are not shared outside of CDC without permission.

At OEU meetings, information may be required from FSEB program consultants responsible for issues to be discussed, EIS Officers, and specific DTBE personnel. The record keeper tracks new reports, monitors open reports (e.g., those pending a final disposition), assembles the minutes of meetings, and prepares summaries for the Office of the Director.

OEU meets at least weekly at a routine time to review all outbreak assessments and reports received by FSEB. The first part of the meeting is to discuss new reports and to make recommendations. The second part of the meeting is to discuss open reports. The FSEB program consultants who are responsible for the areas under discussion might be asked to present at various times throughout the meeting.



A report can be closed after OEU members determine that they have sufficient information for making recommendations. After a report is closed, members of OEU can reopen if subsequent

events require attention or if state or local health officials request further consultation.

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The unit keeps a running log of the reports reviewed and the outcomes. Each RTT form is to include a final disposition. Quarterly the unit reports to all the DTBE Branch Chiefs and the Office of the Director on total numbers of RTT forms reviewed, summary of outcomes, and the number of reports still under review.

OEU also holds ad hoc meetings that are convened by the outbreak response teams for debriefing (see later) after an investigation. OEU uses the information for trouble shooting and for evaluation of this plan and its related activities.

III. DTBE Outbreak Response

After reviewing each report, the evaluation unit recommends a plan of action to the Office of the Director and SEOIB and FSEB Branch Chiefs. If OEU cannot achieve consensus, the plan of action is determined by the Office of the Director. The options for recommendations include –

- No further action;
- Monitor the events through the FSEB program consultant;
- Request additional information from the local agency, through the FSEB program consultant, to help in determining the recommendations for action;
- Designate a team to provide telephone consultation to the agency;
- Provide assistance for an EIS Officer currently assigned to the state or local

agency;

- Provide onsite consultation to the agency;
- Provide onsite assistance in the form of an EPI-AID investigation.

Communicating recommendations to health departments or other agencies

In communicating recommendations to agencies outside of CDC, DTBE staff focus on the primary goal of interrupting ongoing tuberculosis transmission. In general, DTBE staff promote DTBE participation in tuberculosis outbreak activities in accordance with the redoubled national efforts for tuberculosis elimination. DTBE can provide expertise for consultation, organization, data collection and analysis, and special studies for epidemiologic investigations. In addition, assistance may also be provided for intervention design and implementation, program evaluation, and training recommendations and resources. Recommendations for active, on-site participation from DTBE are to be presented with respect for local autonomy and decision making, with the roles of DTBE and local agencies creating a public partnership based on mutual cooperation and participation. DTBE staff strive to accomplish OEU recommendations in a manner which will lead to a positive experience for everyone involved, and they consider the effects of any communication and actions as a reflection of DTBE and all CDC.

For the process of communicating OEU recommendations to an agency with a possible outbreak or related issues, OEU nominates presenters who have the responsibility for contacting the

agency about the recommendations. Usually FSEB consultants are the presenters, and a group is not necessary. (If an on-site investigation is recommended, the FSEB and SEOIB Branch Chiefs should be consulted for the selection of the presenting group.) The group is briefed concerning the details of the situation, and they prepare agenda items for discussion with the local agency. The agenda is shared with the corresponding agency (e.g., state health department) in advance.

The presenting group holds a conference call with the corresponding agency to share the OEU recommendations and to learn about the needs of the agency. The group informs the SEOIB and FSEB Branch Chiefs of the conference content and outcome by e-mail. FSEB consultants facilitate any negotiations based on long-term relationships with local agency officials and staff.

Nature of on-site responses by DTBE

The design of the on-site response depends on whether an EPI-AID was requested by the corresponding agency. An EPI-AID is recommended in this plan as the routine DTBE on-site response to a tuberculosis outbreak. EPI-AID investigations for TB are initiated after a request from a state official, generally the state epidemiologist or a designee who has responsibility for TB. The official or office extending the request for assistance has ultimate responsibility for decisions about the conduct and oversight of the investigation. For an EPI-AID, some of the personnel, the on-site supervisory chain, and the initial structure of the intervention are defined elsewhere in the guidance issued by the Epidemiology Program Office (EPO), CDC (1). It is then the goal of DTBE to build upon the EPI-AID foundation to suit the situation.

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As the response of choice, the EPI-AID has distinct benefits for DTBE and the requesting agency (usually a state health department). An EPI-AID offers a prompt response, and the convenient administrative details of the EPI-AID are familiar to both state epidemiologists and CDC administrators. It offers a line of emergency funding from EPO. By participating in an EPI-AID, an EIS Officer gains valuable experience in tuberculosis control, investigative methods, and epidemiology. Sometimes EPO assigns and funds a health-professions student on elective to participate in the field investigation.

For addressing tuberculosis outbreaks, the basic components of an EPI-AID are supplemented by the host agency and by DTBE for several reasons. First, an EPI-AID is designed to be brief, but the investigation and control of a tuberculosis outbreak might take months. Second, an EPI-AID revolves around the work and leadership of an EIS Officer and one or two supervisors, but the investigation of a tuberculosis outbreak might require a team of diverse personnel including members of FSEB and SEOIB -- the leadership of this extended team might be more complex. Third, an EPI-AID traditionally ends when the EIS Officer provides recommendations to the host agency and leave the site. In some instances, DTBE provides assistance to the host agency in implementing the recommendations and in evaluating the effectiveness. DTBE is committed to building local capacity for tuberculosis control, and the containment of an outbreak is an opportunity to enhance the local resources and to assess training needs.

For an EPI-AID, the staff of SEOIB select the supervisory SEOIB personnel who participate in

the investigation. This becomes a special issue when an EIS Officer who is not assigned to DTBE is selected as the lead investigator. When this happens, SEOIB has to invest more effort to train the EIS Officer about tuberculosis epidemiology and to oversee the on-site work. FSEB and CEBSB can assist in this if requested by SEOIB.

For on-site interventions, DTBE has alternatives to EPI-AIDs. Several possibilities are (1) an on-site program review and training-needs assessment leading to recommendations and possibly long-term assistance for enhancing capacity, (2) an epidemiological investigative team that is not based on an EIS Officer and an EPI-AID, (3) a rapid on-site epidemiological assessment resulting in brief recommendations. The Team Leaders and Branch Chiefs of SEOIB, FSEB, the Information Technology and Statistics Branch (ITSB), and CEBSB should consult with the Director of DTBE for selecting a custom intervention for special circumstances when an EPI-AID would not fit the situation, or when one is not requested. However, the principles outlined for determining the roles of those involved in an EPI-AID apply in all settings where CDC provides technical support to states.¹

Involvement of the host agency

The hosting state epidemiologist must be notified of any on-site participation by EIS Officers in an outbreak-related investigations, whether or not an EPI-AID has been requested, and consent for the plan from the state epidemiologist is required. This requirement is in addition to

¹ Reference: 1997-EC-5 CSTE position statement

consultations between DTBE and state or local tuberculosis-control officers.

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An EPI-AID invitation is required for an EIS Officer to investigate on-site formally (i.e., the Officer collects data beyond that already gathered locally, analyzes data, and writes summaries and recommendations). Officer participation in on-site consultations of limited scope (e.g., attending briefing conferences, interviewing health care workers, reviewing data already gathered, or providing recommendations) does not require an EPI-AID invitation but does require consent from the hosting state epidemiologist. EPO should be consulted for ambiguous situations.

The responsibility and jurisdiction for investigating an outbreak and making interventions rests with the host agency (usually a state or local health department): CDC personnel rarely have authority except as delegated by the host agency. The host agency invites CDC to participate, and all DTBE personnel who join in the on-site investigation must acknowledge that they are guests and behave as such.

Each outbreak investigation is an opportunity for DTBE to create alliances with the tuberculosis-control personnel in the host agency. DTBE is committed to enhancing nation-wide capacity and skills. Therefore, DTBE puts a high priority on incorporating host-agency personnel into each investigation from the planning stages onward. The involvement of host-agency personnel facilitates the investigation, contributes to state and local capacity, and increases the support for

implementing DTBE recommendations. It also builds credibility for CDC overall.

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Acknowledging the local expertise and involving the local personnel as full partners will yield long-term benefits. DTBE personnel must not ask local personnel to contribute to the investigation without offering the opportunities of full participation as team members. All requests for on-site assistance of local personnel must be approved through their line of supervision.

Involvement of other divisions and offices at CDC

Frequently, special circumstances in an investigation require the expertise of specialists from parts of CDC besides DTBE. The common topics requiring assistance are international migration (DGMQ, NCID), engineering controls and occupational hazards evaluation (NIOSH), HIV co-infection (DHAP, NCHSTP), mycobacteriology laboratory issues (DASTLR, NCHSTP), and nosocomial transmission (DHQP, NCID).

To formally involve other divisions and offices at CDC, the Branch Chiefs of FSEB and SEOIB consider the requests of their Team Leaders and make recommendations to the Director, DTBE. The Director of DTBE is responsible for appraising the plans and forwarding formal requests for assistance to other parts of CDC. The Branch Chiefs and Team Leaders of FSEB and SEOIB may negotiate the details of the assistance after the Director has secured agreements to participate.

Speed of response

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Many tuberculosis outbreaks are advanced before they are detected, but tuberculosis spreads through an average host population relatively slowly. Therefore, the urgency for speed in starting most investigations is low. Usually time is available to arrange a carefully-planned and well-staffed investigation. On the other hand, critical information can be lost because of delays. The expectation should be to arrive on site as soon as possible after a formal invitation from a host agency.

TB transmission in a highly-vulnerable population can be an emergency requiring a rapid response, or on occasion, external opinions create the sense of urgency. For these instances, the Director of DTBE should work with the Branch Leaders of FSEB and SEOIB for a more rapid response. If an EPI-AID has been requested, the SEOIB Branch Chief should coordinate with EPO in accelerating the response.

Personnel

The Branch Chiefs of FSEB and SEOIB, in collaboration with their Team Leaders, recommend the personnel from their respective branches for an on-site response team, which is composed of the minimum number of people required. The selections are subject to review and changes by the Director of DTBE, who can consult with other Branch Chiefs or other CDC Divisions or Centers for specialized responses.

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The selection of personnel for an on-site response team is based on the nature of the outbreak and the nature of the response. The key determinant is whether or not an EPI-AID is requested. The pertinent details of the outbreak are its location and its scope. The tremendous range of possibilities requires flexibility in selecting the on-site team.

If an EPI-AID has been requested, then the core of the team is an EIS Officer and an SEOIB supervisor for the EIS Officer. State-based EIS Officers have “rights of first refusal” for investigations within their jurisdictions. Because of anticipated increases in the number of state-based EIS Officers, their participation might become more common. For EIS Officer who are assignees of states or anywhere else besides DTBE, additional attention is required in selecting a supervisor from SEOIB. Other personnel for the team should be selected to build upon the EPI-AID framework to provide epidemiologic and programmatic support for the EIS Officer and the local health jurisdiction.

The details of the outbreak determine how many persons are needed, what types of expertise are required, and how long the personnel will need to stay at the site. If the outbreak involves many settings and many contacts, then more personnel are needed. The host agency often has expert personnel who will join the investigative team, which means that fewer CDC personnel are needed.

For each DTBE staff person who does not have outbreak-investigation experience before joining the team, an experienced staff person from among the DTBE personnel should be assigned. The experienced person acts as a task-specific supervisor, even going on site if necessary, to ensure the assimilation of the inexperienced person into the investigative team.

Sometimes the initial phases of the on-site investigation reveal new information that requires an adjustment of the team. More, fewer, or different personnel might be needed. The Branch Chiefs of FSEB and SEOIB jointly present recommendations to the Director, DTBE, for adjustments.

Leadership

Leadership of the investigation must be determined before the on-site work is begun. Leadership relates to job title, professional training, and experience. Sometimes, the circumstances of the investigation require the leadership of someone who does not have the seniority or job title that ordinarily would indicate the leader.

When an EPI-AID is the framework of the outbreak response, the EIS Officer is the designated leader of the on-site CDC investigative team. When an investigation is undertaken without a request for an EPI-AID, the CDC team leadership should be negotiated within DTBE before starting the investigation.

Pre-trip planning

The pre-trip planning includes the logistics of travel and the coordination of the on-site CDC team. Another essential task is building consensus in the team, in anticipation of the entrance interview. Consensus improves the efficiency of the team's work and simplifies the on-site negotiations at the beginning of the investigation. The team should meet at least once before departure for a discussion of the expected design of the investigation, the preliminary objectives, and the roles of the team members, including selecting a spokesperson for the CDC investigative team during the entrance interview. The team should propose its plans for how it will communicate with its supervisory personnel at CDC after the investigation starts, and the supervisory personnel should confirm the expectations for communication.

Anticipating training needs

During an EPI-AID investigation or other type of CDC on-site participation, opportunities for advancing the technical knowledge, skills, or abilities of state or local personnel become apparent. Also, these personnel sometimes request assistance in finding training programs. An outbreak investigation is a powerful training venue for all participants, but most training needs that extend beyond the investigation and into the intervention generally should be addressed with a formal plan. The on-site team should consult with the CEBSB representative from OEU about anticipated training needs. Additional input is available from the Branch Chief, Communications, Education, and Behavioral Studies Branch (CEBSB), DTBE.

A specific training request that arises during the investigation sometimes can be addressed by referring to on-line resources provided DTBE, as well as the three model TB centers, through DTBE's website: <http://www.cdc.gov/tb/>, or by contacting CEBSB directly at 404-639-8135.

For an overview of assessment, development, implementation, and evaluation of tuberculosis education and training, DTBE offers the document "Focus on TB Training—A Practical Guide."

Entrance interview

The entrance interview is a meeting of the on-site CDC team and the host-agency representatives who are participating in the investigation or who have a jurisdictional "need-to-know" about the investigation. This meeting, which takes place before any CDC on-site work begins, is the critical launching point for the entire on-site investigation. As long as 4 hours should be anticipated for the entrance interview. Time that is invested in building consensus at this meeting is rewarded in terms of efficiency during the investigation and acceptance later of the recommendations that are developed by the investigative team.

The attendance at the entrance interview is determined best by a senior official in the host agency, although the CDC personnel should offer suggestions. The entire CDC on-site investigative team should attend.

The content of the meeting is lengthy and is listed here item by item; a senior member of the CDC team should keep notes of the meeting as part of the record of the investigation:

Introductions. The CDC team should introduce each of its members in terms of name, title, expertise, relevant experience, and role in the investigation. In turn, the CDC team needs to know the same information about the other attendants.

Authority. The host agency has the authority to do public health investigations. The CDC team should determine which officials of the host agency or agencies have authority over which investigative activities (e.g., entering facilities and reviewing records). The CDC team has no authority except as delegated by the host agency. Sometimes the authorization takes the form of a brief letter from local officials. This letter lists the activities sanctioned under its authority. Any additional types of activities that are needed after the investigation begins must be discussed with the officials of the host agency for review and approval.

Plans. The CDC team should open the discussion about the investigative strategy by asking the officials from the host jurisdictions to present the outbreak information that has been collected to date. Then, after asking the officials from the host agency for advice on how to start the CDC phase of the investigation, the CDC team should propose a provisional plan of the work that will be accomplished in the first days of on-site work, as well as the overall goals. The plan should be negotiated until it is acceptable to the officials of the host agency.

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Responsibilities. The hosting officials need to know how responsibilities are divided among the CDC team members. The CDC team needs to know who from the host agency is assigned to work with them on site, and what can be expected from them in terms of authority, time commitment, and special expertise. The CDC team also needs to know who should be contacted for requesting information or additional on-site assistance.

Ongoing communications. The CDC team needs to learn about the local “ground rules” for communication (i.e., whom to contact for sharing information). The host-agency officials need to know how to contact the CDC team quickly. Everyone needs to know when routine communications will be made, and with whom. Weekly on-site communications by telephone or conference are helpful for keeping everyone current. For urgent communications (e.g., if “something goes wrong”), point-persons should be designated from among the Atlanta-based CDC supervisory personnel, the on-site response team, and the host agency.

Interim changes in the investigation. The officials of the host agency need to be aware that the interim findings of the investigation usually lead to adjustments of the plans. Examples of adjustments are an extension of the investigation in duration or geographic area, additional investigations for newly-discovered events, special studies of unusual

situations, changes in on-site personnel to fit the circumstances, and curtailment of some activities or the entire investigation. The CDC team should assure the officials of the host agency or agencies that all proposed changes, and in particular changes that require more or different work from the local members of the investigative team, will be referred to the officials for their approval before any changes are made.

Media relations. Communications with reporters from the news media should be managed by a media-relations office at the host agency. The CDC on-site team needs instructions about how to refer reporters to this media-relations office; the public health officials of the host agency need assurance that the CDC on-site team does not discuss the investigation with reporters unless the media-relations office has approved the interaction. The CDC on-site team should ask to have reporters referred to local/host authorities. Atlanta-based supervisors are to keep the Office of Communications at the National Center for HIV, STD, and TB Prevention abreast of any developments which may involve media. Media experts in CEBSB can assist in this.

Publications and reports. The possibility that the investigation will lead to scientific publications or presentations at meetings has to be discussed. Common concerns are (1) protecting the reputation/privacy of persons and entities that have been affected by the outbreak, (2) scientific content that might be discovered because of the investigation, and (3) authorship of the reports. The protection of privacy should be addressed by

describing the maintenance of anonymity but also the legal accessibility of federal documents. The scientific content depends on the circumstances of the outbreak and any special methods that might be used in the investigation. For scientific manuscripts that are based in EPI-AID investigations, authorship and authorship order are not conferred by any specific action, but instead these need to be agreed upon explicitly in a discussion including at least the official or office extending the request, the EIS officer, and the CDC-based supervisors. If an EPI-AID was not requested, then the CDC on-site team should negotiate with the host-agency personnel who are participating in the investigation. Guidance for determining authorship is provided by CDC and by scientific journals. Questions of authorship should be resolved in accordance with these guidelines before starting the investigation.

Data collection and storage

The team should establish comprehensive systems for data collection and storage before undertaking the field work. The common data sources are interviews with persons who are connected to the outbreak and medical records for persons who have been affected. Paper forms and other data items are official records and should be kept in accordance with federal or CDC policies, even after the information has been entered into a computer. Computer files should be copied onto “back-up files” at least daily. Any data including sensitive personal information about individuals should be protected while on-site by taking advantage of a secured data storage space at the host agency.

Communications with DTBE during the investigation

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Before going on-site, the CDC team should make provisional plans for routine communications with the corresponding Branch Chiefs and Team Leaders of SEOIB and FSEB in DTBE. Other CDC personnel can be included for special circumstances (e.g., an investigation in a tuberculosis laboratory). The frequency of routine communications depends on the nature of the outbreak, the progress of the investigation, the composition of the on-site team, the need for consultation with personnel in DTBE, and the DTBE need for information. The frequency of routine communications is expected to decrease during the investigation.

Interim changes in the investigation

Usually the interim findings of an investigation require adjustments in the plans. The on-site CDC team should discuss ideas for changes with the Branch Chiefs and Team Leaders of FSEB and SEOIB, DTBE. Any proposed departures from the original plan that was approved by the officials of the host agency should be presented to them for their input and approval.

Legal questions

Most outbreaks pose a wide range of legal questions. Typical examples are liability for adverse outcomes related to the outbreak, lawsuits, jurisdiction and authority, access to information, and privacy rights of individuals. The CDC on-site team should be vigilant for these issues and should request consultation with the CDC Office of the General Counsel promptly, if these

issues arise. The Counsel can provide direct answers to some questions, but other questions need to be referred to a counsel of the host agency.

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Exit interview

The exit interview is a meeting that gives the CDC on-site team an opportunity to share the findings of the investigation and to promote its recommendations for ending the outbreak. The exit interview should be scheduled as soon as an end to the investigative phase of the outbreak intervention becomes apparent. The attendance of involved parties at the meeting should be as comprehensive as possible. However, the presentation of sensitive information might require judgement in selecting the attendees; the final decisions about attendance are the prerogative of the officials at the host agency, and all the invitations should be made through them.

Part of the success in effecting an intervention depends on making a comprehensive presentation showing team consensus. Investigations routinely uncover gaps in program performance as relevant findings, and the exit-interview presentation should illustrate that CDC does not achieve its goals by “fault-finding.” In advance of the exit interview, the CDC on-site team should plan the contents for the meeting completely. This includes discussing possible objections to the findings and recommendations. The contents typically contain these elements:

Preliminary findings. The presentation should open with a review of the outbreak scenario and the reasons that the CDC on-site team was invited. Then, the CDC team

should describe the methods of the investigation, a summary of the important findings, and an interpretation of the results. The other attendants at the meeting have an opportunity to raise objections and request clarification.

Public health recommendations. The findings of the investigation lead to recommendations. The CDC on-site team must stress that the recommendations are provisional, with written formal recommendations to follow. The reason for proposing the provisional recommendations is to provide an opportunity to the participants from the host agency (1) to raise concerns, (2) to propose alternatives and (3) to take early action.

Plans for ongoing investigation. Because most investigations of tuberculosis outbreaks are protracted and detailed, the provisional recommendations often include plans for further investigative work. The exit interview is the best opportunity to justify the additional work and negotiate the options. Any further studies or investigations require the approval of the officials of the host agency.

Further contributions of DTBE. The officials of the host agency sometimes do not have enough information to request further assistance from DTBE at the time of the exit interview. However, the CDC on-site team should describe the possibilities after reviewing the options with personnel at CDC headquarters. These options include further on-site investigation, training, financial assistance, and direct on-site assistance.

Long-term programmatic interventions

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Tuberculosis outbreak investigations may uncover problems and gaps in the tuberculosis control program of the host agency and elsewhere. These issues might not always be addressed at the exit interview unless immediate programmatic changes are necessary to control the outbreak.

The extensive range of possible programmatic problems and interventions are beyond the scope of this Outbreak Response Plan. However, the on-site CDC team should report their observations to the FSEB program consultant who is assigned to the host state or big city. This consultant should take advantage of the new insights to work with programs officials in making long-term plans for adjustments.

The FSEB program consultant should incorporate the recommendations provided by the on-site CDC team into the criteria for monitoring the corresponding tuberculosis cooperative agreement.

Within a year after the on-site team has issued its recommendations, during a routine site visit the consultant should assess the progress of the state or big city tuberculosis control program in responding to the recommendations. The consultant should write a brief, summary progress for OEU, for consideration in evaluating the long-term impact of on-site investigations.

Intermediate and long-term interventions often include plans for training current personnel at state or local health departments or adding new personnel, some of whom are inexperienced in tuberculosis control. A training needs assessment provides the foundation for training and

education interventions. The needs assessment is the process for determining gaps between current knowledge, skills, and abilities and the ideals. Then, a strategy for training and education can be developed and the resource needs can be estimated. Consultation should be sought from CEBSB, DTBE, for accomplishing this.

Debriefing

Routine debriefing after an on-site response is in two stages. First, upon returning to headquarters, the on-site response team is responsible for addressing OEU to review the operational issues that were notably troublesome during the on-site investigation. These issues include difficulties in functioning as a team (internal conflicts) and conflicts with the host agency or with other entities that might have become involved (external conflicts). OEU is responsible for tracking the issues and working the Office of the Director of DTBE to solve problems and adjust the Outbreak Response Plan to improve DTBE capability.

The second stage of the debriefing is a presentation to all of DTBE at one of the routinely scheduled weekly conference times. The purposes of this presentation are (1) to update Division personnel about the outbreak, (2) to focus attention on special topics that were recognized during the investigation, and (3) to gather advice from Division personnel.

IV. Outbreak Reports

Every field investigation requires an official trip report which is an internal CDC document that

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typically contains results, analyses, and preliminary recommendations for the host agency. Trip reports for investigations other than EPI-AIDs may take various forms, but they generally will follow the content of an EPI-AID trip report. For an EPI-AID, the instruction for the trip report are included in Guidelines for EPI-AID Investigations (1). Trip reports for any field investigation are to be completed within 14 days of the team's return and forwarded, through SEOIB and FSEB clearance, to the Office of the Director of DTBE. A courtesy copy should be provided for the Branch Chief, CEBSB.

The trip report is the foundation for the report to the hosting agency. This report should be sent to the hosting agency, and to other persons as determined by the situation, within 3 business days of DTBE approving the trip report. It should be prefaced with a thank-you letter including an executive summary of evidence, conclusions, and recommendations from the on-site investigation.

EPO does not request formal clearance from the Division or Center for an EPI-AID trip report because the report is a memorandum addressed to the Director, Division of Applied Public Health Training, EPO (1). DTBE does clear these trip reports through the Office of the Director for programmatic consistency. The EPI-AID trip report should be written as a memorandum to the Director, Division of Applied Public Health Training, EPO, with a carbon-copy list including the recipients outside of CDC. A thank-you letter, as described above, should be used a cover sheet to send the carbon copies to the external recipients.

Protection of Human Subjects *Version 12*

Federal policies for the protection human subjects in medical and epidemiologic research are evolving. According to Guidelines for EPI-AID Investigations (1) “EPI-AID investigations are generally considered to be a response to a public health emergency (rather than research)...”

However, for EPI-AIDS and other types of outbreak responses, situations and activities may be considered predominantly research, and specific policies for the protection of human subjects may apply. The CDC investigators and their supervisors are responsible for discerning activities that might constitute human-subjects research and notifying the Associate Director for Science, Office of the Director of DTBE, who is responsible for interpreting policies, keeping the Branch Chiefs of FSEB and SEOIB informed, advising the CDC on-site team about human subject protection policies, and referring consultations to the NCHSTSP Office of the Associate Director for Science. The on-site team and their supervisors at DTBE are required to consider human subjects protection during their investigative activities and to seek clarification, and if needed, review by the CDC Human Subjects Office.

Protection of Confidentiality

Personal identifiers and other confidential information concerning patients, and possibly others (e.g. control-group subjects) are often collected as part of investigations. Paper and computer files containing confidential information are to be stored in locked facilities with access limited to those involved with the investigation at the local agency hosting the investigation. The access

and collection of confidential information is addressed in the host-jurisdiction public health codes, which may need to be invoked to provide access to information.

The confidential information with personal identifiers collected as part of investigations should be the minimal required, and may be stored only at the host public health agency. Whenever possible, personal identifiers should be deleted from records retained by the CDC investigative team. Records (paper or electronic) with personal identifiers should not be stored at CDC unless the investigation would be rendered infeasible otherwise. For all requests under the Freedom of Information Act (FOIA), DTBE needs to determine, in consultation with the Office of General Counsel, what information can be released legally.

Routine Review of the DTBE Outbreak Response Plan

This plan will be reviewed yearly with the goal of revising it after learning what works and what does not. Factors to consider in the review are the experience with the plan, as learned from the debriefings, and its acceptability both inside and outside of CDC. SEOIB, FSEB, CEBSB, and OD will work on the assessment. EPO has an interest in how this plan affects EIS Officers, and this document should be provided to that program when it undergoes revisions. Outside of CDC, opinions and recommendations will be sought informally from health officials who have received CDC responses through this plan. At the time of each review, the next review should be scheduled.

References

1. CDC. Guidelines for EPI-AID Investigations. Third Edition-DRAFT. Available through Division of Applied Public Health Training, Epidemiology Program Office, Centers for Disease Control and Prevention.

Appendix

Table 1. High Risk Settings for Tuberculosis Transmission

Corrections facilities:	Prisons, jails, and detention centers
Educational facilities:	Schools, colleges, universities, child care centers
Health care facilities:	Acute and long term, and nursing home care
Shelters:	Homeless and emergency shelters
Group quarters:	Dorms, camps, barracks, etc.

Table 2. Criteria for the determination of laboratory cross-contamination

A single *M. tuberculosis* culture-positive respiratory specimen regardless of AFB smear status, a single *M. tuberculosis* culture-positive extra pulmonary body fluid specimen regardless of AFB status or a single *M. tuberculosis* culture-positive tissue specimen without evidence of AFB or granuloma on histologic examination.

A *M. tuberculosis* culture-positive specimen collected greater than 30 days after the collection of a *M. tuberculosis* culture-negative specimen. If patient had previous culture-positive specimens, the isolates demonstrate different DNA fingerprint patterns.

A *M. tuberculosis* culture-positive specimen collected greater than 90 days after the start of correct, continuous antituberculous therapy. If patient has a previously positive specimen, the isolates demonstrate different DNA fingerprint patterns.

A patient for whom a caretaker has indicated that a *M. tuberculosis* culture-positive result is clinically inconsistent.

A patient for whom a laboratory worker has indicated that the *M. tuberculosis* culture-positive result is suspected to be false.